IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9331

Bartle, J. July 23, 2014

Robert E. Staggs ("Mr. Staggs" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Joan E. Staggs, the spouse of Mr. Staggs, also has submitted a claim for derivative benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a.

In July, 2012, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Robert L. Rosenthal, M.D. Based on an echocardiogram dated August 26, 2002, Dr. Rosenthal attested in Part II of claimant's Green Form that Mr. Staggs suffered from mild aortic regurgitation[5] and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[6] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $775,800.[7]

In the report of claimant's August 26, 2002 echocardiogram, the reviewing cardiologist, Bryan Lucenta, M.D., stated that "[t]here is mild aortic insufficiency present ...." Dr. Lucenta, however, did not specify a percentage as to

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4. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See id. § I.49.

5. In a handwritten notice, Dr. Rosenthal stated: "See time 1:04:32-39 on study."

6. Dr. Rosenthal also attested that claimant suffered from mitral annular calcification and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

claimant's level of aortic regurgitation. Under the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In September, 2012, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie determined that there was no reasonable medical basis for the attesting physician's representation that Mr. Staggs had mild aortic regurgitation.[8] Dr. Gillespie explained that only "trace [aortic regurgitation] [was] noted on echo[cardiogram] done on 8/26/02."[9]

Based on Dr. Gillespie's finding, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

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8. Dr. Gillespie also found that there was no reasonable medical basis for the attesting physician's finding that Mr. Staggs did not have aortic stenosis as defined by the Settlement Agreement. Under the Settlement Agreement, the presence of aortic stenosis requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)e). Given our disposition with respect to claimant's level of aortic regurgitation, we need not address this issue.

9. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is defined as a JH/LVOTH ratio of less than 10%.

Rules"), claimant contested this adverse determination.[10] In contest, Mr. Staggs argued that it is not the role of the Trust to "second guess" the attesting physician and that deference is to be given to the attesting physician. Claimant also argued that there was a reasonable medical basis for his claim because four cardiologists, including the original reviewing cardiologist, agreed that the August 26, 2002 echocardiogram demonstrated at least mild aortic regurgitation. In support, claimant also submitted declarations from Leon J. Frazin, M.D., F.A.C.C., and Gerald M. Koppes, M.D. In his declaration, Dr. Frazin stated, in pertinent part, as follows:

> 2. I reviewed the echocardiogram disc dated 26 August 2002, and I concluded that the JH/LVOTH was not less than 10% on this study.
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> 3. The parasternal long-axis view was unavailable; therefore, I determined the aortic regurgitation ... level in the apical long-axis view.
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> 4. I was able to do measurements during time frames 1:03:21 to 1:03:36. At these times, the JH was 0.4 to 0.5 cm and the LVOTH was 2.2 cm. Therefore, the amount of [aortic regurgitation] was 18-22% which is consistent with mild [aortic regurgitation].
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> 5. These jets were true regurgitant jets, and they were representative of other jets that were also in the mild range.

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> 6. In my opinion, a finding of mild [aortic insufficiency] had a reasonable medical basis.

Similarly, Dr. Koppes stated, in relevant part, as follows:

> 3. This case has the most obvious aortic insufficiency ... out of all of the diet drug cases I have seen so far. I am certain that the JH/LVOTH ratio is greater than 10%, but some measurements reach the 40% level. The ratio is clearly at least 25%. The ratio is definitely not less than 10%.
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> 4. I specifically found these jets in the apical 5 chamber view from 2:50 to 4:09 and the apical 3 chamber view from 5:30 to 5:45. (Although at least mild [aortic insufficiency] is seen in all views, the best [aortic insufficiency] jets are seen in the color apical 3 chamber view.)
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> 5. All of these jets are true regurgitant jets, and they are representative of other [aortic insufficiency] jets that are at least in the mild range.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gillespie submitted a declaration in which he again concluded that there was no reasonable medical basis for Dr. Rosenthal's representation that Mr. Staggs had at least mild aortic regurgitation. Dr. Gillespie explained, in pertinent part:

> 11. I reviewed both a tape and a disc of the 8/26/02 study. The CD had several inconsistencies. I suspect this is just the way the study was transferred onto the CD but it initially confused me until I went back to the actual tape. There are multiple segments where the tape number skips. For example at 1:22:59 it then skips back to 1:21:21.24. This happens several times. Also, the numbers quoted by Drs[.] Frazin and Koppes do not correlate with

the numbers I saw on the recording. I believe they were mistaking a 0 for a 2, i.e., 1:03 was actually 1:23 but I am not certain because those numbers did not directly correlate with their stated findings when I reviewed the data.

12. The process of reviewing aortic regurgitation ... specifically requires the use of the parasternal long axis view when available. This view is less likely to cause overestimation of [aortic regurgitation] and a true JH/LVOTH height can be measured. Drs. Frazin and Koppes did not comment on the parasternal assessment of [aortic regurgitation], instead referring to 3-chamber and 5-chamber views. Dr. Frazin stated that the parasternal long-axis view was unavailable on the 8/26/02 study.

13. I found that at the beginning of the August 26, 2002 study, the technician recorded the parasternal long axis view from 1:22:12:22 through 1:22:35:28. While the color was only turned on from 1:22:27 through 1:22:35:28, this was adequate to evaluate [aortic regurgitation], and I again determined that [aortic regurgitation] is trace. Dr. Koppes's comment that some measurements on the August 26, 2002 study reached the "40% level" reiterates the importance of measuring [aortic regurgitation] at the appropriate location because [aortic regurgitation] diverges and if measured more proximally will always overestimate the jet size. Claimant had trace aortic regurgitation, and there is no reasonable medical basis to conclude otherwise. There is also no reasonable medical basis to conclude that the Claimant had mild aortic regurgitation in between commencement of Diet Drug use and the close of the Screening Period.

14. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that

> Claimant had mild aortic regurgitation. Claimant had trace aortic regurgitation, and there is no reasonable medical basis for the Attesting Physician's representation of mild aortic regurgitation. There is also no reasonable medical basis to conclude that the Claimant had mild aortic regurgitation in between commencement of Diet Drug use and the close of the Screening Period.

The Trust then issued a final post-audit determination, again denying the claim of Mr. Staggs. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On March 19, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9028 (Mar. 19, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 16, 2013, and claimant submitted a sur-reply on June 6, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through (continued...)

have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for finding that he suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, claimant reasserts the arguments he made during contest. Claimant further contends that

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11. (...continued)
the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

his physicians adequately rebutted the findings of the auditing cardiologist and established a reasonable medical basis for a finding of at least mild aortic regurgitation. In addition, claimant submitted supplemental declarations from Dr. Frazin and Dr. Koppes in which they again opine that the auditing cardiologist is incorrect, that claimant's August 26, 2002 echocardiogram reveals the presence of at least mild aortic regurgitation, that the level of claimant's aortic regurgitation properly was determined in the apical view of claimant's echocardiogram as the parasternal long-axis view was not technically adequate for interpretation, and that the numbering on the echocardiogram is accurate. Finally, claimant asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "guaranteed class members benefits related to valve surgery."

In response, the Trust argues that claimant has not established a reasonable medical basis for Dr. Rosenthal's representation that claimant had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period and that the reasonable medical basis standard does not require that deference be given to the findings of the attesting physician. In addition, the Trust contends that the auditing cardiologist properly interpreted the reasonable medical basis standard. Finally, the Trust asserts that the Settlement Agreement does not "guarantee" claimants supplemental Matrix Benefits.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Mr. Staggs had at least mild aortic regurgitation. Specifically, Dr. Abramson explained, in pertinent part:

> I carefully reviewed the 8/26/02 echocardiogram paying close attention to the meter numbers referred to by all of the cardiologists. The parasternal long-axis views are present and available for analysis of the aortic regurgitant jet. There is minimal aortic regurgitation in this view, too small to measure. Despite the fact that the apical views should not be used to measure the aortic regurgitant jet when the parasternal views are present, I also reviewed the apical views to try to understand what the cardiologists were referring to. I specifically reviewed the meter numbers cited by Dr. Frazin (1:03:21-1:03:36) and Dr. Koppes (I think he meant 1:02:50-1:04:09 and 1:05:30-1:05:45). One of the problems with measuring the jet from the apical views is that you must perform the measurement of the jet height within 1 cm of the valve. "The preferred assessment is based on the proximal jet width or cross-sectional area immediately below the aortic valve, within 1 cm of the valve." (J. Am. Soc. Echocardiography 2003; 16:790). Most of the cardiac cycles do not show the aortic regurgitant jet within 1 cm of the valve, thus the measurement of those jets would be overestimated due to the known divergence of the jet into the left ventricle as you get further away from the valve. I measured jets in 3 cardiac cycles <1cm from the valve at 1-2 mm which is consistent with trace aortic regurgitation. Regarding the pressure half-time measurement obtained by the technologist, it is a very faint aortic regurgitant jet, which is consistent with insignificant regurgitation and thus inaccurate to measure. I measured the previous envelope as a PHT of 550msec, demonstrating the variability of faint jets.

> ....
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> In summary, there is no reasonable medical basis for the Attesting Physician's claim that this claimant has mild aortic regurgitation. This claimant has only trace aortic regurgitation....

In response to the Technical Advisor Report, claimant counters that the Technical Advisor failed to apply the reasonable medical basis standard. Claimant also argues that the Technical Advisor "went far outside the record" in reaching her conclusions. He further contends that the Technical Advisor failed to find that all of the jets identified by claimant's experts were less than mild and that the Settlement Agreement and the Singh method require the Technical Advisor to measure the largest regurgitant jet to determine the level of regurgitation. Finally, according to claimant, he has established a reasonable medical basis for his claim because the auditing cardiologist did not dispute that claimant had mild aortic regurgitation in either the apical views or when using the pressure half-time method.[12]

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12. Claimant initially included with his response to the Technical Advisor Report verified "rebuttals" by Dr. Frazin and Dr. Koppes. Pursuant to Audit Rule 34, the Special Master determined these rebuttals could not become part of the Show Cause Record. Thereafter, claimant filed "objections" to the decision denying the inclusion of these rebuttals in the Show Cause Record and a motion to have them included. According to claimant, in their rebuttals, Dr. Frazin and Dr. Koppes disputed the Technical Advisor's finding that Mr. Staggs did not have at least mild aortic regurgitation. Pursuant to Audit Rule 34, there is no procedure by which the supplemental declarations of Dr. Frazin and Dr. Koppes can become part of the Show Cause Record. See, e.g., Mem. in Supp. of PTO No. 9041, at 9 n.11 (Apr. 5, 2013); Mem. in Supp. of PTO No. 8402, at 12 n.13

(continued...)

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement requires that aortic regurgitation be determined in the parasternal long-axis view unless that view is unavailable. See Settlement Agreement § I.22. Claimant relies on the declarations of Dr. Frazin and Dr. Koppes to support Dr. Rosenthal's representation that claimant had at least mild aortic regurgitation before the end of the Screening Period.

Claimant's reliance on the opinions of Dr. Frazin and Dr. Koppes is misplaced. Dr. Frazin and Dr. Koppes based their opinions on a review of the apical views rather than the parasternal long-axis view of claimant's August 26, 2002 echocardiogram. Dr. Gillespie, the auditing cardiologist, reviewed claimant's echocardiogram and specifically determined that "the technician recorded the parasternal long axis view from 1:22:12:22 through 1:22:35:28. While the color was only turned on from 1:22:27 through 1:22:35:28, this was adequate to evaluate [aortic regurgitation] ...." Moreover, Dr. Abramson reviewed claimant's echocardiogram and determined that "[t]he parasternal long-axis views are present and available for analysis of the aortic regurgitant jet."

Although Dr. Frazin acknowledged the parasternal long-axis view existed on claimant's August 26, 2002

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12. (...continued)
(Feb. 22, 2010). For these reasons, we will overrule claimant's objections and deny the motion.

echocardiogram, he said that it was not available because "aortic regurgitation cannot be visualized." Dr. Koppes asserted, without any further explanation, that the parasternal long-axis view "was not technically of quality to evaluate [aortic insufficiency] (possibly angulation/ or technician)." Thus, claimant has not established that the parasternal long-axis view was unavailable or that it was appropriate for Dr. Frazin and Dr. Koppes to rely on the apical views to determine claimant's level of aortic regurgitation.

While neither Dr. Frazin nor Dr. Koppes offered opinions as to the level of claimant's aortic regurgitation based on the parasternal long-axis view, Dr. Gillespie and Dr. Abramson each determined that there was no reasonable medical basis for finding that claimant had at least mild aortic regurgitation before the end of the Screening Period. Specifically, Dr. Gillespie concluded that the aortic regurgitation was trace and Dr. Abramson determined that it "was too small to measure."[13]

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13. Dr. Abramson also reviewed the apical views in claimant's echocardiogram on which Dr. Frazin and Dr. Koppes rely, and she determined they also did not support a finding of at least mild aortic regurgitation. In particular, she explained that she "also reviewed the apical views to try to understand what the cardiologists were referring to" and determined that "[m]ost of the cardiac cycles do not show the aortic regurgitant jet within 1 cm of the valve, thus the measurement of those jets would be overestimated due to the known divergence of the jet into the left ventricle as you get further away from the valve." Dr. Abramson "measured jets in 3 cardiac cycles <1cm from the valve at 1-2 mm which is consistent with trace aortic regurgitation."

Accordingly, we conclude claimant has not established a reasonable medical basis for finding that he had at least mild aortic regurgitation by the end of the Screening Period.[14]

We do not agree that claimant is entitled to Matrix Benefits under the Seventh Amendment. As an initial matter, the Seventh Amendment specifically states that "[t]he determinations and actions of the Trust on any aspect of a claim for Cash/Medical Services Benefits of a Category One Class Member or Category Two Class Member, or on any claim for the Matrix Election Payment, shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of claims for Seventh Amendment Matrix Compensation Benefits."[15] Seventh Amendment § IX.E. The Seventh Amendment further provides that:

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14. We also disagree with claimant that Dr. Abramson erred by not relying on the largest jet. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." Mem. in Supp. of PTO No. 6997, at 11 (Feb.26, 2007); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." See Mem. in Supp. of PTO No. 6997, at 11.

15. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. Mr. Staggs is a Category Two Class Member, and his claim for Level III Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.

> For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2. of the Settlement Agreement ....

Id. § IX.A.2. (emphasis added). Section IV.B.1.a. of the Settlement Agreement sets forth:

> 1. .... The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B ("Matrix Compensation Benefits"):
>
> a. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive[16] ... by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period ....

As claimant has not established he was FDA Positive by the end of the Screening Period, the Settlement Agreement requires that his claim be denied.

Therefore, we will affirm the Trust's denial of Mr. Staggs's claim for Matrix A-1, Level III benefits and the related derivative claim submitted by his spouse.

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16. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve." Settlement Agreement § I.22.a.